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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

RE: Docket Number 02N-0278
Public Health Security and Bioterrorism Preparedness and Response Act of 2002
Section 307: Prior Notice of Imported Food Shipments
Request for Public Input

Dear Sir or Madam:

Submitted herewith in duplicate are The Procter & Gamble Company's comments in response to FDA's July 17, 2002 request for public input prior to the development of new regulations required by the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 ("Act"). The Procter & Gamble Company ("P&G") is an international consumer product company headquartered in Cincinnati, Ohio that markets consumer products in over 160 countries around the globe. P&G markets products in the US regulated by FDA (food, cosmetics, over the counter ("OTC") drugs, medical devices, dietary supplements, animal foods, and Rx drugs) as well as products regulated by other Federal agencies (laundry detergents, paper towels, and cleaning products).

On June 12, 2002, the President signed the Public Health Security and Bioterrorism Preparedness and Response Act of 2002 into law. This law requires FDA to promulgate new regulations in several sections within 18 months or the law will take effect automatically. P&G strongly endorses FDA's objective to finalize the required regulations within this timeframe. Without final regulations, we believe implementation of the Act could be highly disruptive not only to the US food supply but to US nonfood consumer product manufacturing and distribution systems. We also appreciate the Agency's willingness to seek early input on regulation development and we submit the following comments in the spirit of this cooperative endeavor.

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1. Allow Use of Existing Records and Systems to the Greatest Extent Possible.

Prior to importing a food product or ingredient, the Act requires notice of the identity of the food article, the manufacturer of the article, the shipper of the article, the grower (if known), country of origin, country from which article was shipped, and anticipated port of entry be provided to FDA. Importantly, the Act also requires the Agency to consult with the Secretary of Treasury (US Customs), presumably to ensure consistency and seamless integration with existing and pending import notification requirements.

We strongly suggest FDA implement Prior Notice regulations in a manner that allows maximum use of existing records and systems. This is consistent with Congressional intent to minimize the potential costs, inefficiencies, and interruptions to the US food chain as a result of the Act. Moreover, the current documents created by companies' compliance with current Good Manufacturing Practices ("cGMPs") and other production standards are more than adequate to meet FDA's statutory requirements. Using or linking to existing systems will lessen the economic impact of the Act immeasurably, minimize disruption of food importation and product spot shortages, encourage cross-Agency coordination/cooperation, and increase the probability of high compliance from the onset.

Some existing systems already include most of the information required by the Act. For example, the US Customs Service's Automated Commercial System ("ACS") allows participants to voluntarily file required import data electronically through an Automated Broker Interface ("ABI"). This system encompasses most, but not all, of the elements required by the Act and likely could be modified to meet all the prior notice provisions of the Act. Two other advantages of ACS are that it is already widely used and it is compatible with FDA's OASIS system, allowing electronic transfer of import information. Modifying ACS could yield a seamless method by which FDA could acquire the information required by the Act without forcing a massive overhaul of the existing informational systems or the expensive and potentially cumbersome creation of entirely new systems.

FDA could also use existing tariff codes to satisfy the Act's requirement to meet the required food identity element. While this system alone would not provide all the information required by the statute's prior notice provisions, integrating this with ACS or another preexisting system could result in a system that satisfies the requirements set forth in the Act. In addition, the creation of completely new systems and paperwork requirements could further complicate compliance with many new and pending laws and regulations that will affect importing food products into the US. We encourage FDA to remain aware and involved in these initiatives in order to assure compatibility.

Finally, we recommend FDA's Prior Notice regulation allow multiple entities to submit the notice requirements set forth in the Act. This is necessary because the realities of the food import business dictate that it is not always the food importer that is in the best position to provide the required notice /information to FDA. There will times a shipper,

broker, or agent is in the best position to transmit the documentation to FDA in accordance to the established timeframes.

2. Embrace Expedited and Simplified Systems

FDA regulations and operations should recognize and incorporate systems designed to allow expedited product imports to operate with minimal disruption provided certain criteria are met. These systems could be based upon, or take advantage of existing systems such as the US Customs-Trade Partnership Against Terrorism (C-TPAT), a voluntary program where participants agree to develop and implement a program to enhance security procedures throughout its supply chain in return for "low-risk" treatment at border inspections. With current systems, manufacturers are moving product across the US/Canadian border with less than 2 hours notice.

According to the Act, the purpose of the Prior Intent regulations is to enable articles to be inspected at ports of entry into the US. By using currently existing expedited procedures (or modified versions thereof) to help manage low-risk imports, the Agency will be better able to allocate its resources on high-risk imports. We believe it is in FDA's best interest and in the country's best interest for FDA to adopt or embrace systems designed to increase confidence in low risk shipments. Using expedited systems for low-risk product low risk importers and/or routine shipments would also decrease the potential food chain interruptions and increased costs that would otherwise result from compliance with the Act.

3. Minimum Time Periods for Prior Notice Need to be Shortened

Congress has instructed FDA to develop regulations regarding the necessary lead time for Prior Notice before a shipment arrives at a US port of entry. The Act specifies that the period of time for providing Prior Notice should be the time necessary for FDA to receive, review, and respond to a Prior Notice request. In establishing prior notice timeframes, FDA is to take into account the effect on commerce, the location of the ports of entry, the various modes of transportation, and the types of food being imported. We see this as enabling FDA to establish different times for Prior Notice based on the circumstances of each border, each mode of transportation, and possibly whether a product is enrolled in an expedited program.

The default rules contained in Section 306 specify default timeframe if regulations are not finalized by 12/2003. Imposition of the Act's default minimum would have immediate, far-reaching negative impact on the processing and distribution of foods throughout the US. It is simply too long for products being imported from NAFTA partner countries.

We strongly urge FDA to adopt much shorter minimum periods of time for Prior Notice in order to accommodate companies participating in expedited import systems. This could include one minimum notice period for those products engaging in expedited imports (or those that have been otherwise deemed low-risk) and a second minimum

notice period for products participating in normal priority or high-risk imports. A second possibility could consist of a single system that has the same period of time for Prior Notice requirements but a different FDA timetable for response based on participation in an expedited program or product risk in general. We recommend immediate electronic response for low risk imports.

Our experience indicates that mode of transportation and border proximity are the two most critical variables impacting the time it takes product to travel from facility to the US border. For truck shipments arriving at the US-Canadian border, the time can be less than 2 hours. We expect the same is true on the US-Mexican border. It is our recommendation that truck and railroad shipments arriving at US borders from Mexico and Canada have, at most, a 2-hour minimum time for giving Prior Notice. We recommend a 2 to 4-hour minimum period of time for airplanes and a 4-hour minimum timeframe for ships.

Finally, requiring minimum periods of time for Prior Notice declarations to be longer than those currently being used commercially will create new and challenging security issues for products awaiting import, regardless of whether they are in the possession of the importer of record, the importing shipper, or the firm transferring product between the two. These challenges increase proportionally with longer required storage times.

4. Ingredients Should be Regulated by Intent

Sections 301 through 315 of the Public Health Security and Bioterrorism Preparedness and Response Act should be applied only to food and ingredients intended for use in food. Ingredients intended for use in anything other than food (cosmetics, laundry detergent, OTC drugs, medical devices, etc.) should not be regulated under these Sections once the intent to use them for non-food uses has been established. This is clearly consistent with Congressional intent to protect the food supply.

This issue is of particular importance because ingredients commonly used in food products are also used as components and ingredients in non-food products. In fact, foods, cosmetics, OTC drugs, laundry detergents, and many consumer product formulations contain many of the same ingredients. For example, both a food and non-food product may contain a common colorant (an FD&C Dye), sweetener (saccharin), preservative (sodium benzoate), buffer (calcium phosphate), chelator (citric acid), emulsifier (PEG), flavor (mint), solubilizer (propylene glycol), thickener (carrageenan) and/or humectant (sorbitol). There are alternate ingredients for each functional class cited above that are used in foods and nonfoods alike in the US. The vast majority of nonfood consumer products marketed in the US contain ingredients also found in food products, including the most common of all, water. Because these individual components or ingredients are "food" in some instances and "non-food", in others, FDA should create a system or mechanism to determine the importer/manufacturer/distributor's intended use of the each item in the context of the Act before regulating an item under the Act. Without distinguishing the status of common ingredients based on intended use, companies that import and/or use versatile ingredients automatically would be forced to follow the registration, notice,

recordkeeping and other requirements. Importantly, many non-food businesses using versatile ingredients believe they are exempt from these provisions of the Act and are not represented in these proceedings to date. Moreover, it would likely strain FDA resources to try to enforce the Act in this manner. We recommend a simple statement by the importer/manufacturer/distributor should suffice to determine which ingredients are "foods" subject to the Act. For example, if we import food grade citric acid for shipment to a detergent facility for use entirely for laundry detergent, Prior Notice, recordkeeping and registration per the Act should not be required. However, since an FDA inspector, without further disclosure, is going to have a preconceived expectation that Prior Notice is required, we believe product intent should be permitted to be declared if known and that this will be sufficient for FDA to allow import.

A primary factor distinguishing factor between drugs, devices, cosmetics and foods is product intent as indicated in the following definitions in the Federal Food, Drug and Cosmetic Act:

> §201(f), defines "food" to be "Articles used for food or drink for man or other animals, 2) chewing gum, and 3) articles used for components of any such article."
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> §201(g) defines "drug" to be "Articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals, and articles (other than food) intended to affect the structure or any function of the body of man or other animals and articles intended for use as a component of any articles specified [above]".
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> §201(h) defines "device" to be "an instrument, apparatus, implement, machine, contrivance, implant, in vitro agent, or other similar or related article, including any component, part, or accessory.....intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease in man or other animals"
>
> §201(i) defines "cosmetic" to be "Articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into or otherwise applied to the human body or any part thereof for cleansing, beautifying, promoting attractiveness, or altering the appearance and articles intended for use as a component of any such articles."

Importantly, these definitions also cover the components of these products. The ingredients of a drug product are regulated as drugs. The ingredients of a cosmetic are regulated as a cosmetic. The components of a food are regulated as a food.

Since the product lines of many US companies, including P&G, encompass both food products and nonfood products that use common ingredients, the new legislation appears to require us to distinguish when a common ingredient is and is not a food. We believe the best approach to determine what items should and should not be regulated under the Act is to require the responsible parties to declare their intended use of articles to FDA upon distributing or importing. For example, a common food ingredient such as sodium saccharin would be regulated as a food if the facility declared it would be used in foods. If saccharin were declared for use only in cosmetics, however, it would not be subject to the Act.

5. Country of Origin

Clear guidance is needed to determine the country from which the food product or food ingredient originates. When a shipment is comprised of a single agricultural product that has been grown in multiple countries and mixed in a single bin, importers need to know how to determine how to appropriately define the incoming article's country of origin. The Act states "country" of origin, not "countries" of origin, suggesting one country is needed. When a product is formulated and ingredients from several countries are combined, what is the finished product's country of origin? The procedure defining country of origin need to be clear, straightforward and timely; an importer shouldn't have to spend days or weeks trying to untangle complex definitions.

We believe country of origin questions should be addressed by employing concepts such as mixtures and "substantial transformation", similar US Customs. An article is a mixture if it is composed of multiple discrete components or multiple sources of the same component that once combined are homogenous. The location where a mixture is created would be the country of origin. When a product has been changed irreversibly (substantially transformed) through processing – cooking, extracting, reacting, purifying, and its original identity has been altered, the country of origin should be the location where this process occurred. Extracting sugar from sugar cane, commingling grain from multiple countries, and baking bread are all examples of processing that would establish a new country of origin. Without recognizing these realities in the commodity and other food industries, it would be difficult for US companies to continue to provide food at reasonable prices to US consumers.

As FDA develops the regulations for notification prior to import, we encourage the Agency to take maximum advantage of the systems already in place. They have evolved over a number of years to be efficient and the entire food distribution system has been built around this expected efficiency. In our opinion, the more FDA can embrace or merely modify these systems to meet the objectives and requirements of the Act, the less disruptive the implementation of the Act will be. We encourage the Agency to adopt periods of time for Prior Notice that are as short as possible to facilitate truck imports from Canada and Mexico.

The Procter & Gamble Company appreciates the opportunity to comment on this new rule and I would be happy to discuss any of these comments in more detail. I can be contacted at (513) 983-0530 or guay.cb@pg.com.

Sincerely,

THE PROCTER & GAMBLE COMPANY
North American External Relations

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